REMARKS

Rejections of Claims and Traversal Thereof

In the December 11, 2003 Office Action,

claims 20 and 22 were rejected under 35 U.S.C. §112, second paragraph;

claims 1-5, 20 and 22 were rejected under 35 U.S.C. §101;

claims 1-5, 20 and 22 were rejected under 35 U.S.C. §112, first paragraph;

claim 4 was rejected under 35 U.S.C. §102(a) as being anticipated by Adams MD, et al., Genbank Sequence Database (Accession Q9VD60) or Lee Cy, et al., August 2000, *Molecular Cell*, 6:433-443; and

claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Baehrecke, EH et al., 1995, *Development Biol,* 171, 85-97, in view of Sambrook, et al. 1989 Molecular Cloning, A Laboratory Manual, 2nd Ed., Cold Spring Press, Cold Spring Harbor, p. 16.3-16.4 and Lee Cy, et al., August 2000, Molecular Cell, 6:433-443.

These rejections are hereby traversed, and reconsideration of the patentability of amended claims herein is requested, in light of the ensuing remarks.

Rejection under 35 U.S.C. §112, second paragraph

Claims 20 and 22 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claims 20 and 22 to recite that the polypeptide is either SEQ ID NO. 2 or a variant of SEQ ID NO. 2 having specifically defined characteristics. Accordingly, this amendment obviates the rejection under 35 U.S.C. §112, second paragraph and applicants request the withdrawal of same.

Rejection under 35 U.S.C. §101

Claims 1-5, 20 and 22 were rejected under 35 U.S.C. §101 because, according to the Office, the claims are directed to a non-statutory subject matter. Applicants have amended the claims according to the suggestion of the Office thereby obviating this rejection. As such, applicants request the withdrawal of this rejection under 35 U.S.C. §101.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1-5, 20 and 22 were rejected under 35 U.S.C. §112, first paragraph for multiple reasons that will be addressed individually hereinbelow.

According to the Office, one skilled in the art would be forced to perform undue experimentation to practice the presently claimed invention. Applicants disagree.

The Office has stated that while the specification is enabling for the polypeptide SEQ ID NO: 8 that induces cell death, it does not provide reasonable enablement for a polypeptide that modulates "programmed cell death" or "apoptically active" polypeptide comprising SEQ ID NO: 2 or SEQ ID NO: 8 and variants thereof. Further, the Office states that the term "modulate" can mean induce or inhibit programmed cell death of apoptosis. Applicants have amended the claims to recite that the polypeptides of the claimed invention "induce cell death." Thus, the claims clearly define that the modulation of apoptosis involves "induced cell death."

According to the Office, based on protein homology, one cannot predict that the full length human E93 of SEQ ID NO: 8 would have similar functions as that of the full length Drosophila E93 of SEQ ID NO: 10, such as inducing apoptosis or programmed cell death, nor that the human E93 fragment of SEQ ID NO: 2 would have similar function as that of Drosophila E93 fragment of SEQ ID NO: 1, which is however not known. The Office further states that the specification does not provide reasonable enablement for numerous variants of the full length human E93 of SEQ ID NO: 8, which comprises SEQ ID NO: 2 or variants of the length Drosophila E93, which comprises SEQ ID NO: 1. In response applicants have amended the claims to recite that the claimed polypeptides consists of SEQ ID NO: 1, SEQ ID NO: 2 or SEQ ID NO: 8 and any variant thereof wherein the variants include conservative substitutions. Applicants further insist that the claims as now amended can be practiced without undue experimentation.

To be enabling, the specification must simply set forth "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112. To demonstrate the lack of enablement, the Office must demonstrate that one of skilled in the art cannot, without undue experimentation, determine and use the claimed polypeptides of the present invention. Applicants note that a need for some experimentation does not result in a failure to satisfy the enablement requirement. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 37 U.S.P.Q.2d 1618 (Fed. Cir. 1996). The *PPG* Court stated that even where some experimentation is necessary to reduce an invention to practice, the enablement requirement is satisfied where: (1) the experimentation is routine; or (2) the specification provides "a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention."

Applicant has provided specific criteria in the recited claims that provide ample guidance regarding the scope of the claims and how to practice the claimed invention. For example, the variants must meet the following parameters including:

(1) at least 90 % homology to SEQ. ID NO. 2;

(2) a conserved carboxy end region having an amino acid sequence of amino acid residues 39 to 53 of SEQ ID NO. 2; and

(3) conservative changes in any amino acid substitutions; and

(4) induces cell death.

Applicants submit that the characteristics defining the variants are easily determined by one skilled in the art. Thus any variant must meet the standards setforth in the claims. Specifically, determining the homology is well known and the Office has provided such a tool by describing a MPSRCH search to determine homology. Any substitution in the variant must include a conservative substitution and these types of substitutions are certainly well known to one skilled in the art. Moreover, as stated by the Office at page 35 of the December 11, 2003 Office Action, Sambrook, et al. provides methods for elucidating structure-function relationships by analyzing the properties of normal and mutant proteins. The variant must further include a conserved carboxy end region having an amino acid sequence of amino acid residues 39 to 53 of SEQ ID NO. Clearly, determining an amino acid linear sequence is certainly within the skills of one knowledgeable in the techniques used in biological sciences and which are usually taught in an undergraduate biology course.

The present specification provides sufficient guidance to determine if a variant induces cell death such as described in Example 2 of the specification wherein a testing method is setforth giving ample guidance to determine the activity of any variants recited in applicants' claimed invention. Therefore, the instant application provides sufficient and enabling information for a person of ordinary skill in the art to practice applicants' invention as recited in claims 1-3, 20, 22 and 26-33. Applicants correspondingly respectfully request the withdrawal of this rejection under §112, first paragraph.

Rejections under 35 U.S.C. §102(a) and §103(a)

Claim 4 was rejected under 35 U.S.C. §102(a) as being anticipated by Adams MD, et al. Genbank Sequence Database (Accession Q9VD60) or Lee Cy, et al. August 2000, Molecular Cell, 6:433-443 (hereinafter Lee); and rejected under 35 U.S.C. §103(a) as being unpatentable over Baehrecke, EH et al, 1995, Development Biol, 171, 85-97, in view of Sambrook, et al. 1989 Molecular Cloning, A Laboratory Manual, 2nd Ed., Cold Spring Press, Cold Spring Harbor, p. 16.3-16.4 and Lee.

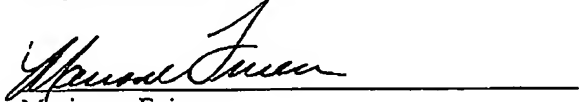
Applicants have cancelled claim 4 thereby obviating these rejections. Accordingly, applicants request that the rejections under 35 U.S.C. §102(a) and 35 U.S.C. §103(a) by withdrawn.

Method and Use Claims to be Rejoined

Applicants have added new claims 29-33 that include product claims and method of use claims wherein the method of use claims recite all the limitations of the product claims. When the product claims are found allowable, applicants request that Examiner Davis rejoin the method of use claims.

There is no additional fee required for the new claims because applicants have paid for 25 claims to date, including 14 independent claims and the application currently includes 18 pending claims, 12 of which are independent. In the event any fee or charge is properly payable in connection with the entry of this Amendment the United States Patent and Trademark Office is hereby authorized to charge the amount to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,



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PATENT APPLICATION
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